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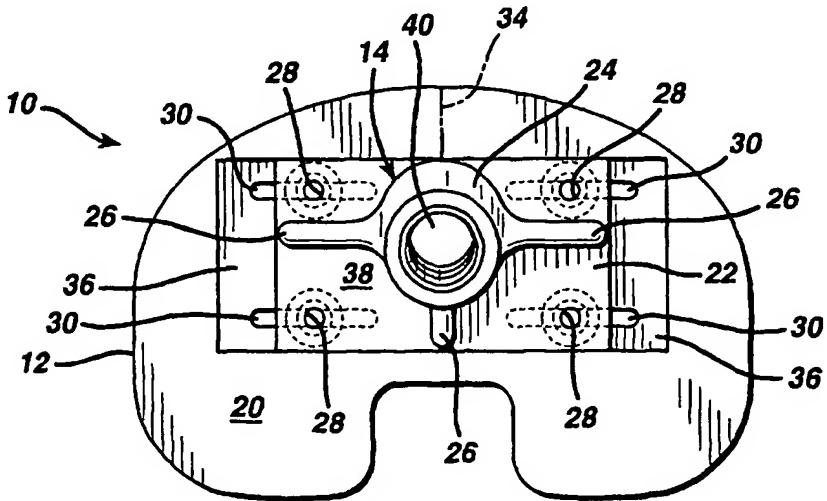
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(54) Tibial tray with adjustable keel

(57) A tibial prosthesis includes a tibial platform having a medial-lateral center and an inferior surface mateable with a resected proximal tibia, and a modular keel

that is fixable to the inferior surface and adjustable in a medial-lateral direction with respect to the medial-lateral center of the tibial platform.

FIG. 2



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Description**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable.

FIELD OF THE INVENTION

[0003] The present invention relates to a tibial prosthesis having a tibial platform and a modular keel that is adjustable in a medial-lateral direction with respect to the platform.

BACKGROUND OF THE INVENTION

[0004] Total knee arthroplasty involves implantation of new articulating surfaces for the tibia, femur and patella. The most common technique for providing new articulating surfaces for the tibia involves resecting an upper portion of the tibia then attaching a prosthetic implant to the tibia over the resected surface. A typical tibial implant includes a tibial tray adapted to abut the resected surface of the tibia and a bearing portion which includes the new tibial articulating surfaces. The tibial tray has a shape that is adapted to generally approximate the shape of the resected surface of the tibia so that the implant generally aligns with the resected surface when the tray is properly attached to the tibia.

[0005] The tibial implant may also include a stem and a keel. The keel extends from an inferior surface of the tray into the patient's bone so as to provide both fixation and positional stability. The stem extends from the inferior surface of the tray or from an inferior surface of the keel into the central canal of the patient's tibia.

[0006] In many tibial prostheses the stem and keel extend from a central position in the base. For some patients however the central canal of the tibia is not located centrally with respect to the tibial articulating surfaces. With these patients, orthopedic surgeons must undertake additional positioning steps to ensure that the tibial prosthesis is properly seated and that it articulates properly with the femoral prosthesis. This problem can be particularly acute in revision surgery where an existing tibial prosthesis is being removed and a new tibial prosthesis is being implanted. When the original tibial prosthesis is removed in revision surgery, often portions of the tibia to which the prostheses are attached become damaged during the removal process or lack viable bony support for the replacement tibial prosthesis. It therefore becomes necessary to attach the new prosthesis farther down into the central canal of the patient's tibia than the original prosthesis. In revision surgery a long stem is typically used with the tibial prosthesis to

ensure good distal fixation of the prosthesis within the canal. The use of long stems however exacerbates positioning problems for patients whose anatomic canal is not centrally located with regard to the tibial articulating surfaces, potentially forcing the surgeon to compromise coverage of the resected tibia.

[0007] Accordingly, a need exists for tibial prostheses with keel and stem portions that can be variably positioned in the medial-lateral direction in order to provide the best possible fit for tibial prostheses for patients whose anatomic canal deviates from standard locations with respect to the tibial articulating surfaces, particularly for use in revision surgery. United States Patent No. 5,271,737 discloses a tibial prosthesis with an offset stem. This stem however is fixed in position and is not adjustable. Accordingly, it won't provide the best possible fit for patients whose tibial canal deviates from the dimensions of this tibial prosthesis. There still exists a need for a tibial prosthesis with an adjustable keel that will allow surgeons the flexibility to treat patients whose tibial canal may not only be not centered but which might be offset in the medial-lateral direction by an unknown amount.

25 SUMMARY OF THE INVENTION

[0008] The present invention provides a tibial prosthesis having a tibial platform with a medial-lateral center and an inferior surface matable to a resected proximal tibia. A modular keel is fixable to the inferior surface of the platform and is adjustable in a medial-lateral direction with respect to the medial-lateral center of the tibial platform.

[0009] The tibial platform may include at least one slot extending in a medial-lateral direction with at least one mating element extending through the at least one slot to secure the modular keel to the tibial tray at a preselected offset from the medial-lateral center of the tibial tray.

[0010] In an alternative embodiment, the tibial prosthesis may include a rotating disc that is fixed at its center to the medial-lateral center of the tibial tray. The disc may further be fixed to the modular keel at a position on the disc that is offset from the center of the disc. The rotating disc may then be oriented to provide a preselected medial-lateral offset between the medial-lateral center of the tibial tray and the modular keel.

[0011] In a further embodiment, the modular keel has a preselected offset in a medial-lateral direction with respect to the medial-lateral center of the tibial platform. This modular keel may be selected from a group comprising a plurality of modular keels having different preselected offsets in a medial-lateral direction with respect to the medial-lateral center of the tibial platform.

[0012] The tibial prosthesis may also include a stem receivable within the central canal of a patient's tibia. The stem may be integrally formed with the modular keel, or the stem may be modular and matable with the

keel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The invention will be more fully understood by reference to the following detailed description when considered in conjunction with the accompanying drawings, in which:

FIG. 1 is an anterior view of a tibial prosthesis of the invention having an adjustable keel;

FIG. 2 is an inferior view of the tibial prosthesis of FIG. 1;

FIG. 3 is a side view of the tibial prosthesis of FIG. 1;

FIG. 4 is a cross sectional view of modular stem useful with the tibial prosthesis of the invention;

FIG. 5 is an anterior view of an additional tibial prosthesis of the invention having an adjustable keel;

FIG. 6 is an inferior view of the tibial prosthesis of FIG. 5;

FIG. 7 is an anterior view of a further tibial prosthesis of the invention having an adjustable keel attached to a rotating disc;

FIG. 8 is an anterior view of an asymmetric tibial tray useful with the prosthesis of FIG. 7;

FIG. 9 is an inferior view of the tibial tray of FIG. 8;

FIG. 10 is an anterior view of the rotating disc of FIG. 7;

FIG. 11 is an inferior view of the rotating disc of FIG. 10;

FIG. 12 is an anterior view of a further tibial prosthesis of the invention having an offset modular keel;

FIG. 13 is an inferior view of the tibial prosthesis of FIG. 12; and

FIG. 14 is a side view of the tibial prosthesis of FIG. 12.

DETAILED DESCRIPTION OF THE INVENTION

[0014] A tibial prosthesis 10 of the invention, illustrated in FIGS. 1 to 3, includes a tibial tray 12 or platform and a modular keel 14. The tibial tray 12 has a superior surface 16 defining a central tibial plateau region bounded by a peripheral rim 18. The tibial tray 12 has an inferior surface 20, opposed to the superior surface 16, that is generally shaped to mate with a proximal portion of a tibia that has been surgically resected for the purpose of executing a total knee arthroplasty. The superior surface 16 is designed to mate with a tibial bearing member (not shown). A variety of means for attaching a bearing member to a tibial tray are well known in the art and the present invention is not particularly limited to a specific bearing member or means for mounting a bearing member on the tray 12. The tray 12 and the modular keel 14 are preferably formed from a metal useful for prosthesis applications such as stainless steel or metal alloys, including titanium alloys.

[0015] A modular keel 14, matable to the inferior surface 20 of the tibial tray 12, has a superior, tray mating portion 22 and a keel portion 24. As illustrated in FIGS. 1 to 3, the keel portion 24 includes wing elements 26 extending in the medial, lateral and posterior directions. In other embodiments, the number and shape of the wing elements, as well as the angles at which they extend, may vary.

[0016] Modular keel 14 includes four threaded apertures 28 on its superior, tibial tray mating portion 22 that correspond to four slots 30 on the tibial tray 12. The slots 30 on the tibial tray 12 are elongate in a medial-lateral direction and are arranged so that when mating elements, such as screws 32, are inserted through each of the slots 30 to engage threaded holes 28, the modular keel 14 may slide in a medial-lateral direction with respect to the tibial tray 12 as the mating elements slide in the elongate slots 30. The slots 30 may be chamfered or have other means to permit the screws 32 to be seated at or below the superior surface 16 of the tibial tray 12 so that the screws 32 do not interfere with the positioning of a tibial bearing member. Generally, the slots 30 allow the modular keel 14 to be adjusted to provide a medial-lateral offset of up to at least about 8 millimeters in the medial or lateral direction from a medial-lateral center 34 of the tibial tray 12.

[0017] Tibial tray 12 may also include a recessed region 36 on its inferior surface 20. The recessed region 36 is generally of the same shape as the tray mating portion 22 of the keel 14, but is elongated in the medial-lateral direction so that when the tray mating portion 22 is placed within the recessed region 36, adjustability of the modular keel 14 is limited to the medial-lateral direction. Preferably, the depth of recessed region 36 is equal to the thickness of tray mating portion 22 of the modular keel 14 so that the inferior surface 38 of the tray mating portion 22 is flush with the inferior surface 20 of the tray 12.

[0018] The illustrated modular keel 14 also includes a generally cylindrical stem mating element 40 defining an aperture having internal threads designed to mate with a modular stem component 42 (FIG. 4). A person of ordinary skill in the art will recognize that a modular keel 14 of the invention may include an integral stem, or may provide other means for the modular keel 14 to

mate with a modular stem 42, such as by forming a taper interlock between male and female tapered surfaces in place of threads located on the modular keel 14 and stem 42.

[0019] A modular stem 42, as shown in FIG. 4, includes a mating portion 44 and a fixation portion 46. The fixation portion 46 is elongate and generally cylindrical and may be attached to the central canal of a tibia using bone cement or non-cemented methods. Generally, for revision procedures, long stems which extend into the isthmus of the tibial canal are used. Typical cemented long stem embodiments have a length ranging from about 30 to 60 millimeters, while non-cemented stem embodiments have a length ranging from about 75 to 150 millimeters.

[0020] In a further embodiment, shown in FIGS. 5 and 6, the modular keel 14 may be adjustably attached to the tibial tray 12 using a single mating element 32. In this embodiment, the tibial tray 12 includes a single slot 30 and the modular keel 12 includes a single threaded aperture 28 for attachment to the tibial tray 12. In general, the number of mating elements 32 may be varied by a person of ordinary skill in the art in keeping with the spirit of the invention.

[0021] As shown in FIGS. 7 to 11, medial-lateral adjustability of the modular keel 14 may also be provided using a rotating disc 48. In this embodiment, a rotating disc 48 is attached to the inferior surface 20 of tibial tray 12 (an asymmetric tibial tray 50 usable with the invention is illustrated in FIGS. 8 and 9) by a mating element, in this case a screw 32. The rotating disc 48 has a central aperture 52, for mating with the screw 32 and may be rotated about the central aperture 52 at least before the screw 32 is tightened. An offset aperture 54 is spaced apart from the central aperture 52 and seats a mating element, such as screw x, through the offset aperture 54 to attach the modular keel 14 to the rotating disc 48. In use, the modular keel 14 is attached to the rotating disc 48 at the second aperture 54, the rotating disc 48 is rotationally oriented so that the modular keel 14 extends at the desired medial-lateral offset 56, and the rotating disc 48 is fixed to the inferior surface 20 of tibial tray 12.

[0022] An additional tibial prosthesis 10 having an adjustable keel is illustrated in FIGS. 12 to 14. In this embodiment, the medial-lateral offset 56 is provided on the modular keel 14 itself by offsetting the keel portion 24 in a medial-lateral direction with respect to the tibial tray mating portion 22 of the modular keel 14. Tibial tray mating portion 22 mates with the tibial tray 12 using four screws 32 that are located at fixed positions with respect to the tibial tray 12 - though more or fewer screws 32, or other mating elements in place of screws, may be used to attach the offset modular keel 14 to the tibial tray 12. A recessed region 36 may be provided on the interior surface 20 of the tibial tray 12 having a shape substantially similar to the shape of the tibial tray mating portion 22 of the modular keel 14 and having a depth

that results in the inferior surface 38 of the tibial tray mating portion 22 being flush with the inferior surface 20 of the tibial tray 12 when the modular keel 14 is fixed to the tray 12.

5 [0023] In a preferred embodiment, a plurality of modular keels 14 having varying offsets are provided. Typical offsets might include 4, 5, 6, and 8 millimeter offsets in the medial and lateral directions as well as a modular keel having a neutral position (0 millimeter offset). With 10 such an embodiment, a surgeon may adjust keel and stem offsets for a particular patient by selecting an appropriate modular keel from the group of modular keels having different offsets. Where the angle α between the keel portion 24 and the tibial tray 12 in the anterior-posterior plane is 90° , it may be possible to use a single modular keel 14 to provide an offset in either a medial or a lateral direction by reversing the orientation of the modular keel 14.

15 [0024] It will be understood that the foregoing is only 20 illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. All references cited herein are expressly incorporated by reference in their entirety.

25

Claims

- 30 1. A tibial prosthesis comprising:
a tibial tray having a medial-lateral center and an inferior surface matable with a resected proximal tibia;
a modular keel fixable to the inferior surface and adjustable in a medial-lateral direction with respect to the medial-lateral center of the tibial platform.
- 35 2. The prosthesis of claim 1, further comprising a stem receivable within the central canal of a tibia.
- 40 3. The prosthesis of claim 2, wherein the stem is modular and matable with the modular keel.
- 45 4. The prosthesis of claim 1, wherein the tibial tray includes at least one slot extending in a medial-lateral direction and at least one mating element, fixable to the modular keel, extends through the at least one slot to secure the modular keel to the tibial tray at a preselected offset from the medial-lateral center of the tibial tray.
- 50 5. The prosthesis of claim 4, wherein four mating elements secure the modular keel to the tibial tray.
- 55 6. The prosthesis of claim 1, wherein one mating element secures the modular keel to the tibial tray.

7. The prosthesis of claim 1, further comprising a rotating disc fixable at its center to the medial-lateral center of the tibial tray and also being fixable to the modular keel at a position on the disc that is offset from the center of the disc.

8. The prosthesis of claim 7, wherein the rotating disc is oriented to provide a preselected medial-lateral offset between the medial-lateral center of the tibial tray and the modular keel.

9. The prosthesis of claim 1, wherein the modular keel is adjustable to provide a medial-lateral offset between the modular keel and the medial-lateral center of the tibial tray that is at least about 8 millimeters in the medial or lateral direction.

10. The prosthesis of claim 1, wherein the modular keel has a tray mating portion matable with the inferior surface of the tibial tray and a keel portion having a fixed offset in a medial-lateral direction with respect to the tray mating portion wherein the modular keel is selected from a group comprising a plurality of modular keels having different fixed offsets.

11. The prosthesis of claim 10, wherein the group comprising a plurality of modular keels having different fixed offsets includes at least a modular keel having an offset of about 4 millimeters in the medial direction.

12. The prosthesis of claim 10, wherein the group comprising a plurality of modular keels having different fixed offsets includes at least a modular keel having a neutral offset.

13. A tibial prosthesis comprising:

- a tibial platform having a medial-lateral center and an inferior surface matable with a resected proximal tibia; and
- a modular keel fixable to the inferior surface and having a preselected offset in a medial-lateral direction with respect to the medial-lateral center of the tibial platform.

14. The prosthesis of claim 13, wherein the modular keel has a preselected offset of about 4 millimeters in the medial direction.

15. The prosthesis of claim 13, wherein the modular keel is selected from a group comprising a plurality of modular keels having different preselected offsets in a medial-lateral direction with respect to the medial-lateral center of the tibial platform.

16. The prosthesis of claim 13, wherein the modular keel includes a substantially flat platform mating portion having an inferior surface, and the tibial platform has a recessed region defined on its inferior surface, wherein the platform mating portion seats within the recessed region so that the inferior surface of the platform mating portion is substantial flush with the inferior surface of platform when the modular keel is fixed to the tibial platform.

portion having an inferior surface, and the tibial platform has a recessed region defined on its inferior surface, wherein the platform mating portion seats within the recessed region so that the inferior surface of the platform mating portion is substantial flush with the inferior surface of platform when the modular keel is fixed to the tibial platform.

17. The prosthesis of claim 13, further comprising a stem receivable within the central canal of a patient's tibia.

18. The prosthesis of claim 13, wherein the stem is modular and matable with the modular keel.

FIG. 1

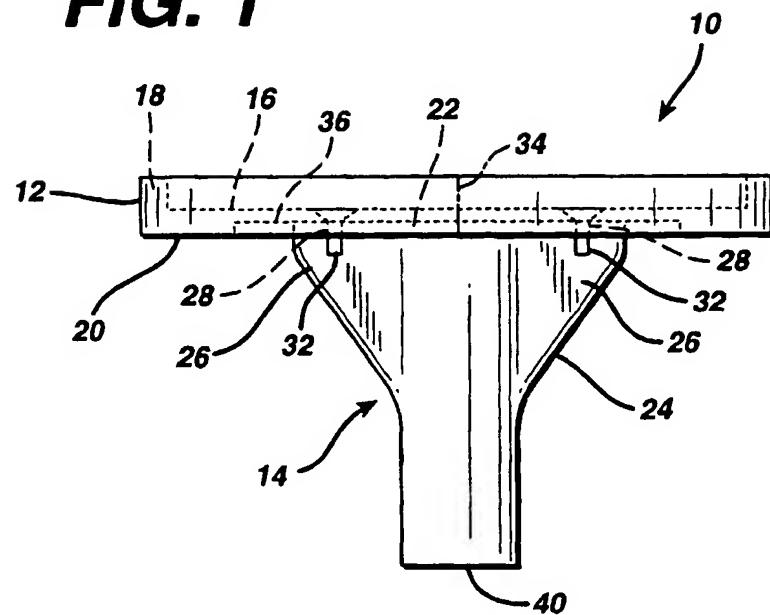


FIG. 2

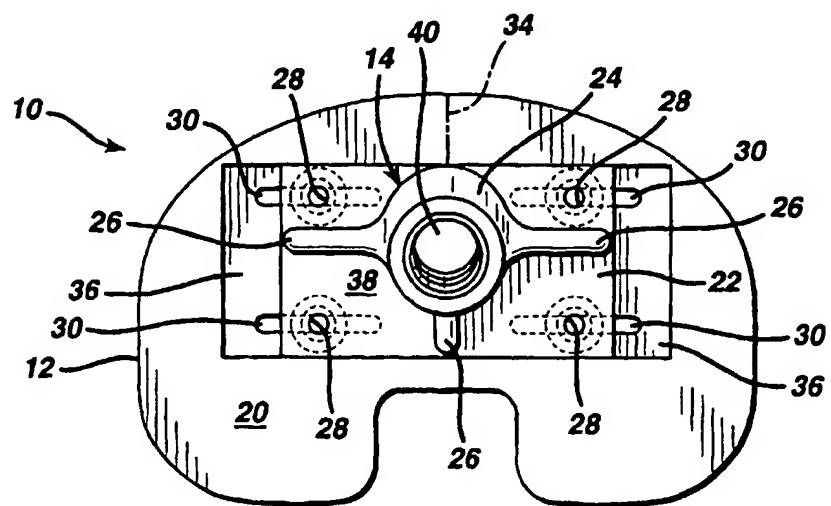


FIG. 3

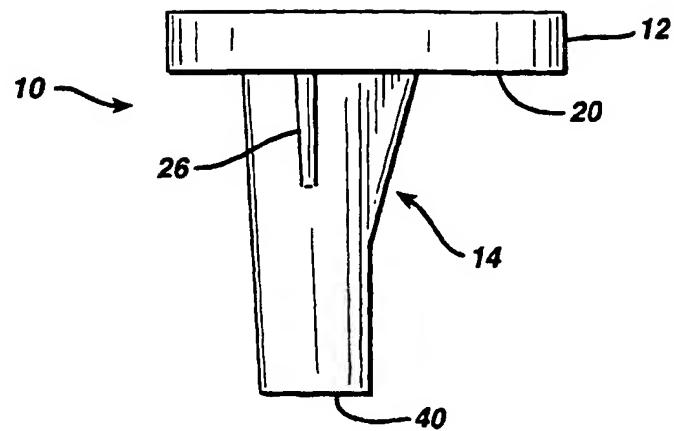


FIG. 4

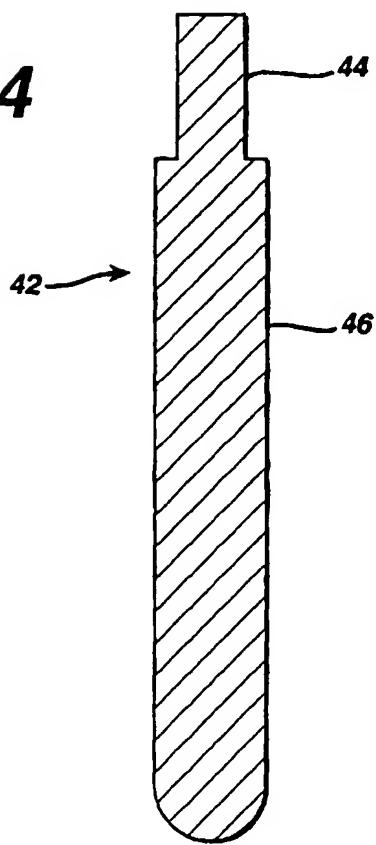


FIG. 5

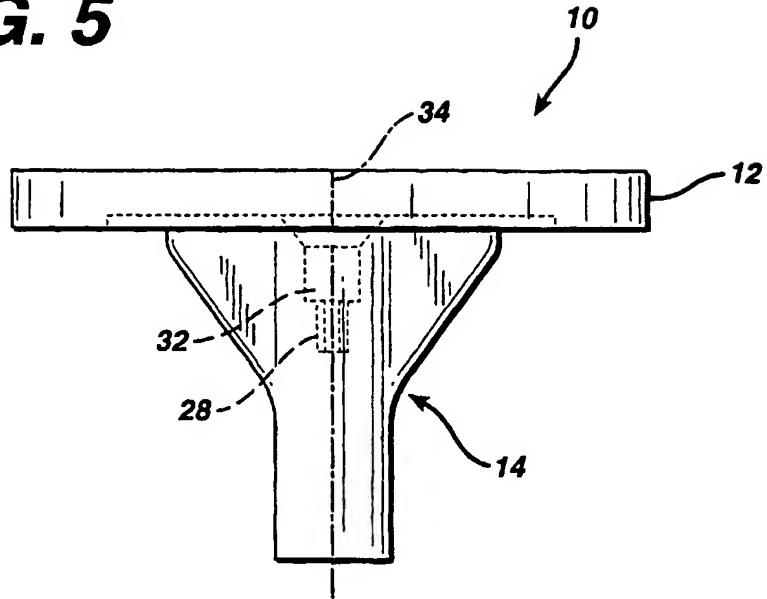


FIG. 6

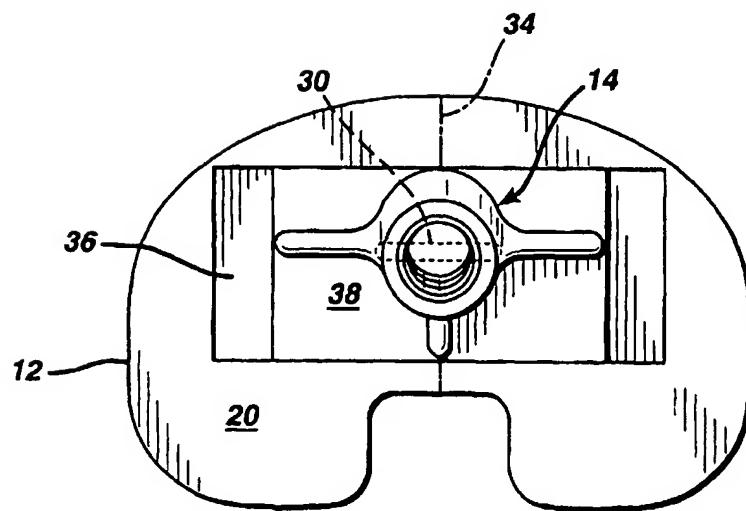


FIG. 7

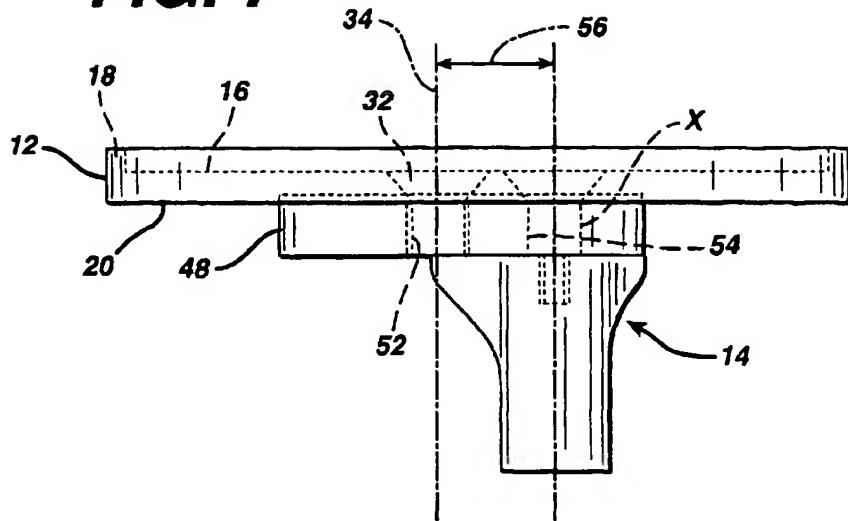


FIG. 8

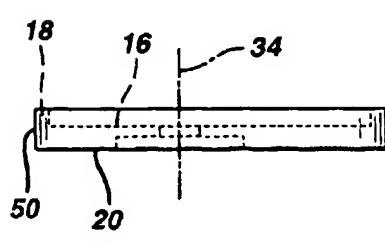


FIG. 10

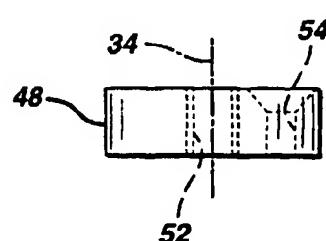


FIG. 9

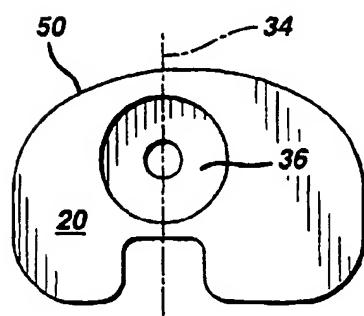


FIG. 11

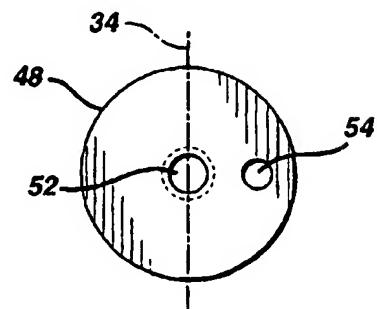


FIG. 12

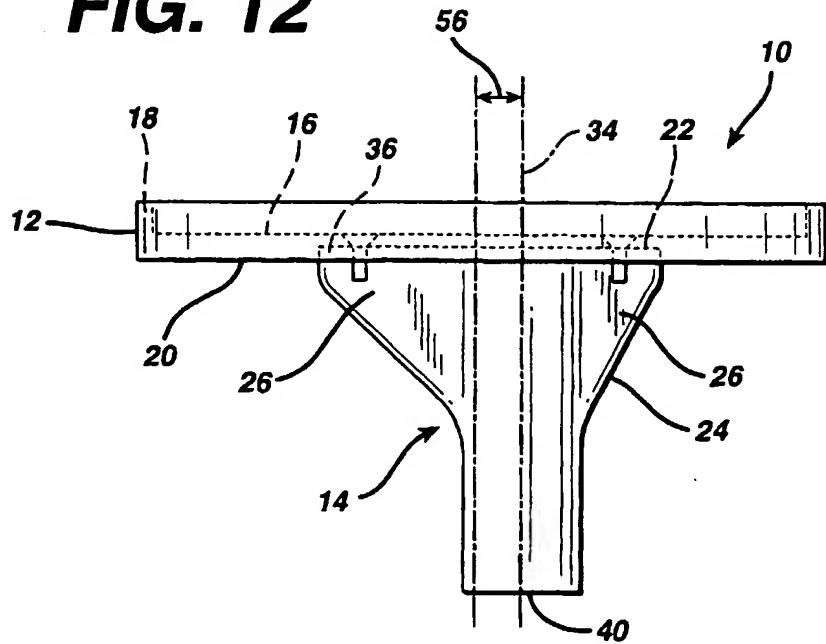


FIG. 13

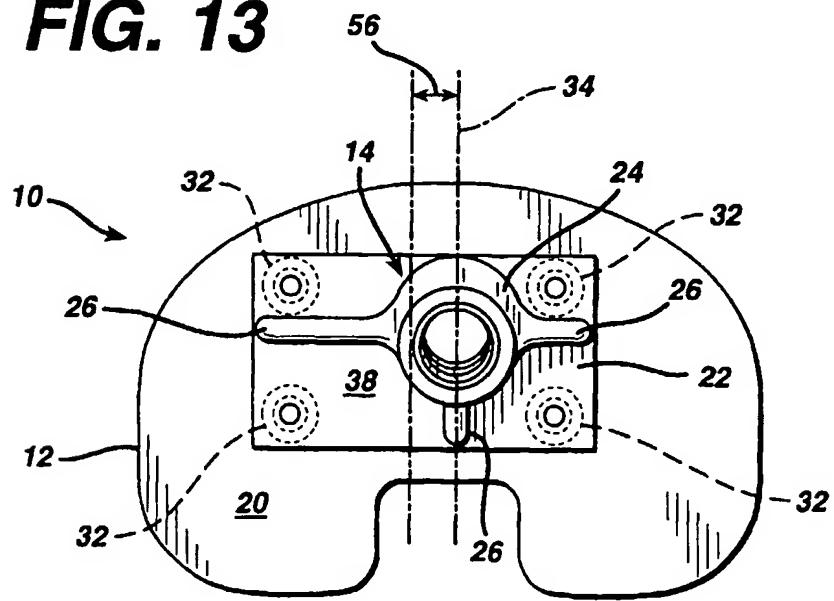
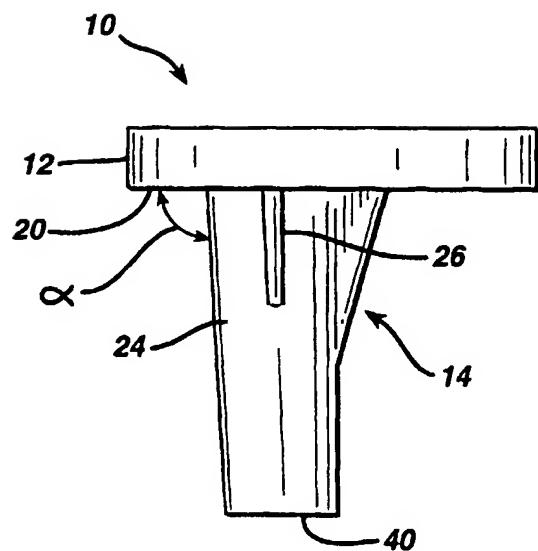


FIG. 14





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 99 30 3705

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)						
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim							
D,Y	US 5 271 737 A (BALDWIN JAMES L ET AL) 21 December 1993 (1993-12-21) * abstract; figures * ---	1,13	A61F2/38						
Y	US 5 290 313 A (HELDRETH MARK A) 1 March 1994 (1994-03-01)	1,13							
A	* column 3, line 30 - line 44; claim 1; figure 9 *	2,7							
A	FR 2 748 389 A (RECH APPLIQUEES AUX TRAITEMENT) 14 November 1997 (1997-11-14) * page 7, line 8 - line 11; claims; figure 5 *	1,2,7, 10,13							
P,X	US 5 879 391 A (SLAMIN JOHN E) 9 March 1999 (1999-03-09)	1,13							
A	* column 5, line 48 - column 6, line 24; figures 7-10 *	2,4,6							
	-----		TECHNICAL FIELDS SEARCHED (Int.Cl.6)						
			A61F						
<p>The present search report has been drawn up for all claims</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Place of search</td> <td style="width: 33%;">Date of completion of the search</td> <td style="width: 34%;">Examiner</td> </tr> <tr> <td>BERLIN</td> <td>1 September 1999</td> <td>Kanal, P</td> </tr> </table>				Place of search	Date of completion of the search	Examiner	BERLIN	1 September 1999	Kanal, P
Place of search	Date of completion of the search	Examiner							
BERLIN	1 September 1999	Kanal, P							
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document							
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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 3705

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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01-09-1999

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US 5290313	A	01-03-1994	NONE	
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US 5879391	A	09-03-1999	NONE	

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82